UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC., Plaintiff, v. NATERA, INC., Defendant.	Case No. 18-cv-01662-SI **ORDER DENYING MOTION TO DISMISS** Re: Dkt. No. 24

Before the Court is defendant Natera's motion to dismiss plaintiff Illumina's complaint. Dkt. No. 24. After hearing argument and considering the parties' materials, the Court rules as follows.

BACKGROUND

This patent infringement action concerns U.S. Patent No. 9,493,831 ("the '831 patent"). Plaintiff Illumina develops, manufactures, and markets life science tools and integrated systems for large-scale analysis of DNA. Case No. 15-cv-2216, Dkt. No. 1 at ¶ 4. Defendant Natera provides non-invasive diagnostic testing for determining fetal chromosomal abnormalities. Compl. at ¶ 3.

The '831 patent, titled "Methods for Fetal Abnormality Detection," is directed to methods for "selectively enriching non-random polynucleotide sequences," "generating libraries of sequences," and "detect[ing] fetal aneuploidy." *See* U.S. Patent No. 9,493,831, at [54], [57] (filed Apr. 2, 2015). The patent claims priority to a provisional application filed in January 2010 and issued to Illumina in November 2016. Dkt. No. 24 at 3. Illumina asserts the '831 patent is a continuation of the '430 patent, and improves the method for the creation of synthetic DNA

libraries for aneuploidy analysis. Dkt. No. 32 at 1. Specifically, the '831 patent "allows one to prepare DNA libraries targeting non-random DNA sequences that facilitate aneuploidy detection… that expedite downstream analysis of the DNA library." Dkt. No. 32. Claim 1 of the '831 patent is representative of the method and appears as follows:

> A method for preparing a sequencing library from a maternal blood sample, the method comprising:
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> a. obtaining a maternal blood sample comprising fetal and maternal cell-free DNA;
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> b. selectively enriching a plurality of non-random polynucleotide sequences of genomic DNA from said fetal and maternal cell-free DNA to generate a library of enriched non-random polynucleotide sequences, wherein said plurality of non-random polynucleotide sequences comprises at least 100 different nonrandom polynucleotide sequences selected from a chromosome tested for being aneuploid, said enriching comprising:
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> (i) a first amplification step to generate a plurality of first reaction products, said amplification comprising at least 100 first primers configured to amplify at least 100 different non-random polynucleotide sequences;
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> (ii) a second amplification step to generate a second reaction product, said amplification comprising a second set of primers comprising sequences contained in the first reaction products; and
>
> (iii) a third amplification step to generate a third reaction product comprising said library of enriched non-random polynucleotide sequences, said amplification comprising a third set of primers comprising sequences contained in the second reaction products;
>
> wherein at least one primer of at least one of the second and third sets of primers includes a sequence configured to be added to the different non-random polynucleotide sequences to permit the enriched non-random polynucleotide sequences of the library to anneal to a same sequencing primer for the enriched non-random polynucleotide sequences of the library.

'831 Patent col. 63 l. 39-col. 64 l. 42.

In February 2013, Natera began selling the Panorama™ Natera Prenatal Screen, a non-invasive prenatal test for Down syndrome. Dkt. No. 1 at 3. In March 2018, plaintiff filed a lawsuit accusing defendant's prenatal test of infringing the patent-in-suit. Compl. at ¶¶ 14, 18. Natera moves for a motion to dismiss under Rule 12(b)(6) for patent ineligibility under 35 U.S.C.

§ 101. Dkt. No. 24 at 1. Natera argues the claims of the '831 patent are not eligible for patenting because they are drawn to patent-ineligible (naturally occurring) subject matter and are void of any inventive concept. Dkt. No. 24.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a district court must dismiss a complaint if it fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "facial plausibility" standard requires the plaintiff to allege facts that add up to "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While courts do not require "heightened fact pleading of specifics," a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 570.

To state a claim for patent infringement, "a patentee need only plead facts sufficient to place the alleged infringer on notice. This requirement ensures that the accused infringer has sufficient knowledge of the facts alleged to enable it to answer the complaint and defend itself." *Phonometrics, Inc. v. Hospitality Franchise Sys., Inc.*, 203 F.3d 790, 794 (Fed. Cir. 2000). The Federal Circuit has "repeatedly recognized that in many cases it is possible and proper to determine patent eligibility under 35 U.S.C. § 101 on a Rule 12(b)(6) motion." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1373 (Fed. Cir. 2016).

DISCUSSION

Under Section 101 of Title 35 of the United States Code, the scope of patentable subject matter encompasses "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." *Bilski v. Kappos*, 561 U.S. 593, 601 (2010) (quoting 35 U.S.C. § 101). Section 101 "contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (internal quotations omitted). They are not patent-eligible because "they

are the basic tools of scientific and technological work," which are "free to all men and reserved exclusively to none." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (internal quotations omitted). The United States Supreme Court has explained that allowing patent claims for such purported inventions would "tend to impede innovation more than it would tend to promote it," thereby thwarting the primary object of the patent laws. *Id.* at 71.

In *Alice*, the leading case on patent-eligible subject matter under § 101, the Supreme Court refined the "framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts" originally set forth in *Mayo*. *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 566 U.S. 66). This analysis proceeds in two steps.

> The first step looks to determine whether claims are directed to a patent-ineligible concept. If they are, the second step is to consider whether the additional elements recited in the claim transform the nature of the claim into a patent-eligible application by reciting an inventive concept that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.

Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015) (internal quotations and citations omitted).

I. Directed Towards a Patent-Ineligible Concept

The "'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed.Cir.2015)) (citing *Genetic Techs.*, 818 F.3d at 1375 (Fed.Cir.2016)). "The courts have recognized that it is not always easy to determine the boundary between abstraction and patent-eligible subject matter." *Internet Patents*, 790 F.3d at 1347 (Fed. Cir. 2015) (citing recent precedent highlighting patents that attempt to preempt use of the laws of nature or abstract ideas when determining the boundary). *See also Parker v. Flook*, 437 U.S. 584, 589 (1978) ("The line between a patentable 'process' and an unpatentable 'principle' is not always clear.").

Regarding patent-ineligible concepts, the Supreme Court has held that there is a "rule against patents on naturally occurring things . . . ." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013). The Supreme Court ruled that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Id*. at 589 (citing *Mayo*, 132 S. Ct. at 1293) (internal quotations omitted).

Natera argues the '831 patent is directed towards a patent-ineligible concept because it is concerned primarily with obtaining a library that contains non-altered DNA sequences that are naturally occurring. Dkt. No. 24 at 13-14. Natera also argues the addition of sequence tags or indexing sequences does not make the patent eligible, as the tags "do not otherwise alter the naturally occurring genetic information contained in the DNA sequences of interest." Dkt. No. 24 at 15.

Illumina responds that the '831 patent is directed towards a "novel *method* of preparing a synthetic nucleic acid library comprised of non-naturally occurring nucleic acid molecules" Dkt. No. 32 at 8. Illumina argues that the resulting DNA is not naturally occurring "because all of the claims recite the use of primers in the second or third round of amplification that include either the sequences for a same sequencing primer (claim 1) and/or an index sequence (claims 2-3 and 14)." Dkt. No. 32 at 15.

The Court looks to analogous cases for guidance. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Federal Circuit held the patent at issue (the '540 patent) was directed towards patent-ineligible subject matter, affirming this Court's ruling. 788 F.3d 1371, 1373 (Fed. Cir. 2015) ("The steps of the method of claim 1 of the ′540 patent include[d] amplifying the cffDNA contained in a sample of a plasma or serum from a pregnant female and detecting the paternally inherited cffDNA."). The Federal Circuit explained the claims of the '540 patent were "directed to a multistep method that starts with cffDNA taken from a sample of maternal plasma or serum—a naturally occurring non-cellular fetal DNA . . . ." *Id*. at 1376. The Federal Circuit held that "[t]he method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring." *Id*. The Federal Circuit noted that "the claims at issue, as

informed by the specification, are generally directed to *detecting* the presence of a *naturally occurring thing or a natural phenomenon*, cffDNA in maternal plasma or serum." *Id.* (emphasis added).

The claims of the '831 patent similarly use cffDNA, beginning with samples of naturally occurring "fetal and maternal cell-free DNA." '831 Patent col. 63 l. 41-42. The '831 patent is also directed towards amplifying specific sequences of the cell-free DNA and detecting fetal aneuploidies. *See* '831 Patent at [57]. Like the claims in *Ariosa* that were directed to the detection of naturally occurring cffDNA, the claims of the '831 patent only enable aneuploidy detection if the non-random sequences retain their natural arrangement. Consequently, the method claims of the '831 patent also "end[] with a natural phenomenon." *See Ariosa*, 788 F.3d at 1376. Accordingly, based on the currently available information, the Court finds that the '831 patent is directed towards patent-ineligible subject matter.

II. Inventive Concept

An inventive concept occurs when "the claims are "more than a drafting effort designed to monopolize the [abstract idea]" and "the claims may be read to 'improve[ ] an existing technological process.'" *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1351 (Fed. Cir. 2016) (quoting *Alice*, 134 S. Ct. at 2356-2357 (2014)). Moreover, "well-understood, routine, conventional activity" "is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo*, S. Ct. at 1291 (citing *Parker*, 437 U.S. at 590).

Illumina argues the '831 patent is an inventive concept because it does "not preempt downstream use of any naturally occurring substance" and is tethered to the specific technological realm of analyzing "fetal and maternal cell-free DNA for aneuploidy determination." Dkt. No. 32 at 19. However, "the absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics*, 788 F.3d at 1379. The Court elaborated that "[w]here a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework . . . preemption concerns are fully addressed and made moot." *Id.*

Natera argues the '831 patent does not contain an inventive concept because the selective enrichment of DNA in the patent involves well-known, routine, and conventional amplification techniques. These include polymerase chain reaction (PCR) as well as basic and conventional amplification tools such as primers, sequencing tags, and indexing sequences. Dkt. No. 24 at 16-17. Illumina responds that the '831 patent improves upon prior art techniques by addressing a need for selective enrichment of DNA sequencing for aneuploidy analysis to avoid producing non-target amplification products. Dkt. No. 32 at 18-19.

The Court finds that at this stage in litigation the factual record is not sufficient for the Court to conclude whether there is an inventive concept. Specifically, the Court cannot determine whether the amplification of "at least 100 different non-random polynucleotide sequences" and the performance of "successive rounds of amplification using primers that are directed to sequences *within* the products of prior amplification reactions" are routine or conventional. *See* '831 Patent col. 63 l. 49-50; *See* Dkt. No. 32 at 11. Moreover the Court cannot determine whether the claimed selective enrichment leads to a technological improvement. *See* '831 Patent col. 63 l. 44-51.

Accordingly, the Court DENIES defendant's motion to dismiss.

CONCLUSION

For the foregoing reasons, the Court DENIES the motion to dismiss without prejudice to renew on a fuller factual record.

IT IS SO ORDERED.

Dated: June 26, 2018

SUSAN ILLSTON
United States District Judge